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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,273	04/09/2004	Kenneth Jacobs	00766.000101.1	9860

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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06/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,273	Applicant(s) JACOBS ET AL.	
	Examiner John S. Brusca	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-62 is/are pending in the application.
- 4a) Of the above claim(s) 51-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/29/04, 4/3/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 1 in the reply filed on 03 April 2007 is acknowledged. The traversal is on the ground(s) that a search burden does not exist to search both Groups 1 and 2. This is not found persuasive because a search of both groups would require searching sequence databases for two different polynucleotide sequences, SEQ ID NOS: 75 and 85. Sequence database searches is a resource intensive activity that occupies a limited computer search capability present in the Office. As such, the search burden required to search both groups is sufficient to preclude examination of both groups in a single application.

The requirement is still deemed proper and is therefore made FINAL.

2. This application contains claims 51-62 drawn to an invention nonelected with traverse in the reply filed on 03 April 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

3. The objection to the specification for an improper claim for priority under 35 U.S.C. 120 in the Office action mailed 29 September 2006 is withdrawn in view of the applicant's comments filed 03 April 2007. The applicants have noted a preliminary amendment filed 09 April 2004 that was overlooked by the Office in the previous Office action. The preliminary amendment corrects the original statement of priority in the specification.

Information Disclosure Statement

4. The applicants requested in their comments filed 03 April 2007 consideration of a reference listed in the Information Disclosure Statement filed 29 July 2004 (GenBank version

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No. V90128). Upon further review of the application file of parent Application No. 09/306111, the reference is present in the parent application as originally stated by the applicants. Attached to this Office action is a signed list of references indicating that the GenBank reference has been considered.

Claim Rejections - 35 USC 101 and 112

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from <http://www.uspto.gov/web/menu/utility.pdf>]

"Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

- A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.
- B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. ' 101.)
- C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".
- D. A method of making a material that itself has no specific, substantial, and credible utility.
- E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

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Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, if a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

A "Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

See also the MPEP at 2107 - 2107.02.

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 39-50 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The claimed polynucleotides are not supported by a specific asserted utility because the disclosed uses of the polynucleotides and encoded polypeptides are not specific and are generally applicable to any nucleic acid or encoded polypeptide. The specification states on pages 266-267 that the polynucleotides may be useful as molecular weight markers and chromosomal probes. Similarly, the specification states on pages 266-284 that the encoded polypeptide may be used for further research such as screens for the biological activity of the encoded polypeptide, or used as tissue markers or feedstock. These are non-specific uses that are applicable to polynucleotides

and encoded polypeptides in general and not particular or specific to the polynucleotides and the encoded proteins of the polynucleotides being claimed.

Further, the claimed polynucleotides and encoded polypeptides are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. The specification characterizes the claimed polynucleotide and encoded polypeptide on pages 226-228 as having similarity to several known gene sequences, and especially notes the similarity to *Xenopus* (frog) chordin. The specification notes binding affinities of the encoded polypeptide to several known polypeptides on page 228, and further notes tissues in which the claimed polynucleotide is preferentially expressed. However the specification does not assert a utility for the claimed subject matter at pages 229-228. On pages 266-284, the specification asserts utilities for the claimed subject matter. The specification states that a polynucleotide may be utilized to express a polypeptide. The protein could then be used in conducting research to functionally characterize the polypeptide, as suggested in the specification on pages 267-284. The need for such research clearly indicates that the polypeptide does not have a substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case, the polypeptides produced from processes involving the claimed polynucleotides do not have specific and substantial utilities. The research contemplated by the applicants to characterize potential polypeptide products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a polynucleotide or encoded polypeptide or the mechanisms in which the polypeptide is involved does not define a "real world" context or use. Similarly, the other

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listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well established for the compounds.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 39-50 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

9. Applicant's arguments filed 03 April 2007 have been fully considered but they are not persuasive. The applicants cite *In re Brana* to justify use of post filing evidence to support utility, however post filing evidence cannot be cited to provide what was absent from the specification at the time of filing, only to support that what was described at the time of filing is an enabling disclosure. The specification shows that the claimed polynucleotides encode a polypeptide that binds BMP-2 and BMP-4 at page 228, but the specification does not state whether the binding has any activation or inhibitory effect on the activity of BMP-2 or BMP-4.

The applicants have pointed to Mathura et al. for support for utility of the claimed invention. Mathura et al. merely shows BMP-2 and BMP-4 expression levels in different normal and diseased tissues, and the effect of addition of recombinant BMP-2 and BMP-4 on

proliferation of cultured cells. Mathura et al. is silent on the mode of action or utility of the claimed polynucleotides that encode a polypeptide that binds BMP-2 and BMP-4.

The applicants point to Sakuta et al. for support for utility of the claimed invention. Sakuta et al. discusses a BMP-4 antagonist termed ventropin that the applicants assert is identical to the polypeptide encoded by the claimed polynucleotides. Sakuta et al. is silent regarding a utility for inhibition of BMP-4 activity. Sakuta et al. shows that treatment of embryos with ventropin results in abnormal embryo development. Sakuta et al. shows basic research on ventropin but does not show a practical application for ventropin.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

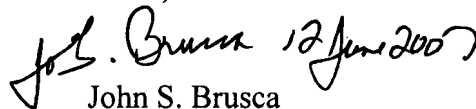
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



John S. Brusca
Primary Examiner
Art Unit 1631

jsb